Remarks/Arguments

Claims 1 and 5-20, all claims pending in the application, stand rejected under 35 USC § 101 and 35 USC § 103. Reconsideration and withdrawal of the other rejections is respectfully requested in view of the above amendments and for the reasons that follow.

The Examiner holds that the claims fail to meet the requirements of 35 USC § 101 because there is no recitation of a machine or transformation present in the claims. Applicants' claims, as now amended, require search of a "computer readable data source that includes the dictation records of at least one healthcare professional". While the exact words "computer readable" are not present in applicants' specification, it is submitted that this language not only meets the requirements of 35 USC § 101, but is not new matter in accordance with the guideline provided by the USPTO in the memorandum released on January 26, 2010, relating in the "Subject Matter Eligibility of Computer Readable Media".

Claims 1 and 5-20 stand rejected under 35 USC § 103 as unpatentable over Davies et al. in view of McAlindon et al. Reconsideration and withdrawal of the rejections is respectfully requested.

The claims of the present invention define a methodology whereby a database of patient information originated by one or more healthcare professional can be searched by a research management organization (RMO) (defined at paragraph [0013] of applicants' specification) to identify prospective clinical trial participants without violating patient confidentiality. Absent the methodology of the claims, the RMO cannot identify and contact prospective participants

because of HIPPA and other confidentiality restrictions.

In accordance with the methodology, as specifically defined in the claims, the RMO, using criteria established for a given trial, researches a database to identify prospective participants, who are identified by non-personal identifiers. Then, for each prospect identified, the RMO contacts the healthcare professional who originally generated the database information. The healthcare professional, who is privy to the patient's identity due to the professional relationship, contacts the prospective participant to determine if there is an interest in participating in the study. If so, the healthcare professional also obtains the prospective participant's permission for the healthcare professional to provide their identity to the RMO. The healthcare professional then provides the identities of consenting prospective participants to the RMO, who can then contact the prospective participants regarding their participation in the study. As a result of this methodology, the RMO expertise can be used to identify and interview prospective participants, minimal time of the healthcare professional is required, and no privacy rights of the prospective participants are violated.

Neither the Davies et al. nor McAlindon et al. references, alone or in combination, teach or suggest a methodology that includes all of these essential steps. Moreover, the references, alone or in combination, fail to achieve the desired results of the claimed methodology. In fact, the references, are directed to unrelated aspects of medical records mining and clinical trial patient recruitment.

Davies et al. describes using a database of electronic medical records to identify potential clinical trial participants. The database is said to be accessible by physicians, clinical research organizations, etc. However, there is no teaching or suggestion of the relationship between a

research management organization, the healthcare professional, and prospective participants.

McAlindon et al. is specifically directed to the identification and testing of clinical trial participants via the Internet. This type of recruitment is in fact discussed in applicants' specification as paragraph [0008]. Advertising media or accessing a potential candidate database is used to solicit candidate participants, who then apply via a website. After a candidate applies, steps are taken to screen the candidates, including the review of medical records or reports (col. 4, ll. 43-44). The investigator may be given permission to contact the candidate's personal healthcare provider. (col 5, ll. 10-12). The healthcare provider may be interviewed to confirm eligibility. (col. 10, ll.24-28). Note that in all instances, the investigator solicits the potential clinical trial participants, and then may contact a healthcare professional or review medical records after the identity of the prospective participant is known.

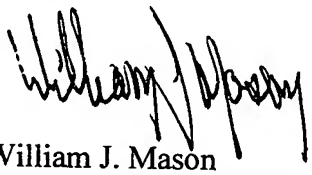
Thus,the methodology used in McAlindon et al. is entirely different for that claimed by applicant. There is no suggestion of identifying prospective participants by researching a database and then having the healthcare professional contact the prospective participant to obtain their consent, thereby avoiding violation of patient privacy rights. Instead, it is the prospective participant (candidate) that gives the investigator permission to contact the candidate's personal healthcare provider. (col 5, ll. 10-12).

It is alleged in the Office Action that the step of "receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial" is taught by McAlindon et al. at col. 4, ll, 26-47. In fact, there is no statement at Col. 4, ll. 26-47, or anywhere else in the patent, similar to what the examiner alleges. Moreover, as noted above, there would never be an occasion for the healthcare professional to provide names of

patients to the investigator. In McAlindon et al., the names are already known to the investigator before the healthcare professional is contacted. Also, prospective participants are not identified in McAlindon et al. via database research using non-personal identifiers, but by Internet solicitation.

Accordingly, in view of the amendments to the claims and for the foregoing reasons, it is believed that this application is now in condition for allowance. Issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,



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